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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,253	01/18/2002	Robert L. Stout	32265	7968

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EXAMINER	
WORTMAN, DONNA C	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,253	STOUT, ROBERT L.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 1-30 as originally filed are pending and under examination.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing as it is unclear what process is being claimed. It is unclear whether "determining an optical density" is a part of, or is in addition to, "performing an HCV antibody-based assay." It is unclear whether "using said determined optical density ..." is intended to represent an active process step or is intended to be language correlating the result of the final, "determining," step with the preamble.

Claim 2 is confusing because it recites "said optical density determining step occurring only on said samples testing positive said HCV antibody-based assay" since the only "antibody based assays" disclosed also involve determining optical density as a part of an immunoassay that uses HCV antigens to determine the presence of HCV antibodies in samples.

Claim 3 is confusing in reciting "said performing step including the step of contacting said sample with a quantity of HCV antibodies" since it is unclear how that step defines an assay for HCV antibodies. Since all the exemplified immunoassays, i.e., "antibody based assays," use HCV antigens to determine the presence of HCV antibodies in samples obtained from individuals, it is not clear what process step is intended in claim 3.

Claim 12 is indefinite because the only process step recited is that of "measuring the optical density of said fluid sample." Since a method claim is defined by process steps, no meaningful method or assay is represented by merely measuring optical density of a fluid sample.

Claims 15-18 are indefinite because each recites a particular optical density value ("less than 1.0"; "less than 2.35"; "greater than about 2.35"; "greater than 3.0," respectively). An optical density value standing alone is meaningless, since optical density values obtained in the course of performing assays depend on, *inter alia*, wave length settings and sample dilutions.

Claim 19 is indefinite because recites "contacting said fluid sample with HCV antibodies to form a solution." It is not clear what method step Applicant intends to claim. Relying on the specification to help interpret the claim, it is noted that the specification teaches, in Example 1, performing a second test using HCV antigen to detect anti-HCV antibodies on samples that had tested positive for anti-HCV antibodies in a first test. It is possible that Applicant intended "contacting ... HCV antigen" rather than "HCV antibodies."

Claims 22-25, like claims 15-18, are indefinite because each recites a particular optical density value ("less than about 1.0"; "less than about 2.35"; "more than about 2.35"; "more than about 3.0," respectively). An optical density value standing alone is meaningless, since optical density values obtained in the course of performing assays can only be interpreted by one with knowledge of such pertinent information as sample

dilutions or the wavelength settings that are determined by the color of the product formed.

Claim 26 is confusing as it is unclear what process is being claimed. It is unclear whether "measuring the optical density" is a part of, or is in addition to, "performing an antibody-based assay." Further, claim 26 recites in the preamble "A method of testing for chronic HCV infection ..." but does not recite any language that would correlate the results of the final "measuring" step with the preamble; lacking such language, the claim is incomplete.

While the claims are indefinite as discussed above, to the extent that at least some of the claims are understood generally to be drawn to a method of correlating a relatively high amount of anti-HCV antibody in a patient sample to the probability that the patient has chronic HCV, the following rejection over prior art is offered.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-11, 12-14, and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/26673, Scheffel et al., cited on PTO 892, attached. Scheffel

et al. disclose the correlation of sustained high titers of anti-HCV antibody to HCV E2 antigen with chronic HCV infection (see, e.g., page 11, lines 1-9). Samples were initially tested for the presence of anti-HCV antibody by commercially available EIA (see page 17, Assay, lines 22-27) and samples testing positive were then further tested to determine the levels, or titers, of anti-HCV antibodies (see page 17, Assay, lines 14-22; Table 1, column headed "PEAK E2 UNITS). Scheffel et al. teach obtaining results of an ELISA using a chromogenic substrate in which the appropriate signal output equates to optical density value of a neat or diluted test sample, and constructing a reference curve from which antibody can be quantitated (see page 13, lines 6-22), as well as testing samples from patients with known chronic and self-limiting HCV infections to establish a "cutoff" value so that correlation values can be established such that one could draw a reasonable conclusion as a patient's HCV status from a single data point (page 12, lines 13-28, e.g.). Scheffel et al. differ from Applicant's claimed method only by disclosing the correlation of the amount of HCV E2 antibodies with chronic infection; however, Applicant's claims recite anti-HCV antibodies broadly and do not distinguish over the teachings of Scheffel. It would have been obvious to one of skill in the art to detect levels or amounts or titers of anti-HCV antibodies in patient samples, using methods that employ an optical density reading to indicate the antibody levels, amounts, or titers, and to correlate a relatively high amount of anti-HCV antibodies with a high likelihood of the presence of chronic HCV, and a relatively low amount of anti-HCV antibodies with a lower likelihood of chronic HCV, based on the teachings of Scheffel et al. regarding anti-HCV E2.

Claims 2, 3, 15-18, and 19-25 are not included in this rejection only because they are so unclear as explained above.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Payan et al. (Annales de Biologie Clinique 61(3):311-317, 2003), not prior art, disclose that the presence of a high level of anti-HCV antibodies in patient sera, expressed in terms of a signal/cutoff ratio, can be used to diagnose chronic HCV.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw